a covering of collagen having an extracellular matrix that becomes remodeled by host tissue, secured to the at least one stent and extending therealong between the proximal and distal ends.

Remarks

In the Office action of July 17, 2002, Paper No. 7, claims 1-11 are pending and were rejected. In particular, claims 1-7, 10 and 11 were rejected under 35 USC 102(b) as being anticipated by Douglas (128). Claims 8 and 9 were rejected under 35 USC 103(a) as being unpatentable over Douglas in view of Cook (931).

By this amendment, claim 1 is being amended to further distinguish the claims over Douglas. In particular, the covering of collagen having an extracellular matrix has been amended to include a particular covering of collagen having an extracellular matrix "that becomes remodeled by host tissue". Support for this amendment can be found in applicant's specification in the paragraph bridging pages 4 and 5. As a result, the covering of collagen in independent claim 1, as amended herein, includes collagen having an extracellular matrix that allows host tissue to grow or remodel into a covering of collagen. As a result, endothelial cells from the lining of a blood vessel grow or remodel into the covering of collagen. As indicated in the cited references in applicant's specification, this remodeling activity is due to growth factors and proteins found in certain types of harvested tissue and in particular small intestine submucosa of pigs. This particular covering of collagen having an extracellular matrix that becomes remodeled by host tissue is not identically disclosed in Douglas. The Examiner cited Hoffman (5,108,424) in col. 2, lines 37-41 of Douglas for a collagen-impregnated Dacron graft. This graft includes a porous synthetic vascular graft substrate formed by knitting or weaving that has at least three applications of dispersed collagen fibrils. Hoffman in col. 3, lines 18-22, indicates that collagen coating 16 is formed from at least three applications of an aqueous collagen fibril plasticizer dispersion which has been cross-linked by exposure to formaldehyde vapor. In lines 36-45, the cross-linked

collagen forms a slurry which is deposited on the Dacron and allowed to dry. As a result, the collagen graft has essentially zero porosity. In examples 1 and 2 provided in col. 3 and 4, the collagen slurry is obtained from fresh calf skins that are mechanically and chemically treated to obtain a pure bovine collagen. The indicated mechanical and chemical processing thus produces a collagen that is incapable of forming a covering of collagen having an extracellular matrix that can become remodeled by host tissue as claimed in applicant's independent claim 1, as amended herein. Applicants submit that the chemical processing of Hoffman eliminates or deactivates any growth factors or proteins in the extracellular matrix of the bovine collagen. Furthermore, applicants submit that the unprocessed bovine collagen does not have any growth factors or proteins that would facilitate tissue remodeling. Thus, applicants submit that Douglas does not identically disclose applicants' stent graft of independent claim 1, as amended herein, that includes a covering of collagen having an extracellular matrix that becomes remodeled by host tissue, and it is requested that the rejection of amended independent claim 1 and dependent claims 2-7, 10 and 11 under 35 USC 102 (b) as being anticipated by Douglas, be withdrawn.

Claims 8 and 9 dependent on amended independent claim 1 were rejected as being unpatentable over Douglas in view of Cook. In dependent claim 8, the covering of collagen is a sleeve of small intestine submucosa material. In dependent claim 9 dependent upon claim 8, the sleeve is defined by connecting together along a seam, opposite edges of at least one flat tissue of the small intestine submucosa material. The Examiner in his rejection of claims 8 and 9 indicated that it would have been obvious to modify the graft of Douglas with the graft of Cook to increase the biocompatibility of the implant and reduce the chance of rejection by the body. Applicant traverses such contention. Applicant submits that the examiner has failed to establish a prima facie case of obviousness. First, there is absolutely no suggestion in either of Douglas or Cook to combine the teachings thereof and produce applicants' claimed invention. Second, Douglas is directed to forming a collagen slurry directed to the problem of porosity. Third, as

previously indicated, the collagen slurry covering does not include any growth factors or proteins that would remodel host tissue as claimed in applicant's invention. Cook is directed to an extracellular matrix of collagen that can remodel host tissue, but there is absolutely no discussion in Cook of using the new SIS material in combination with a stent as claimed in applicants invention. Lastly, it was applicants specification that made direct reference to Cook of which the Examiner used hindsight in his combination with Douglas. Thus, applicant submits that there is no motivation or suggestion in Douglas and Cook to combine them to form applicants claimed invention, and it is further submitted that the Examiner has failed to establish a prima facie case of obviousness. In view thereof, applicants submit that dependent claims 8 and 9 are not taught or suggested by Douglas and Cook, either singly or in combination, and it is requested that the rejection of these claims under 35 USC 103(a) as being unpatentable over Douglas in view of Cook, be withdrawn.

The reexamination and reconsideration of this application is respectfully requested, and it is further requested that the application be passed to issue.

Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' attorney requests a telephone interview with the Examiner to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment.

Respectfully submitted,

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Date: Oct. 10, 2002

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Enclosures: Marked-up copy of amended claims (1sheet)

MARKED-UP COPY OF AMENDED CLAIMS

1. (Amended) A stent graft comprising:

at least one stent having a proximal end and a distal end and having a lumen extending therethrough between the proximal and distal ends, and

a covering of collagen having an extracellular matrix that becomes remodeled by host tissue, secured to the at least one stent and extending therealong between the proximal and distal ends.